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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/335,686	06/18/1999	RANDOLPH J. NOELLE	012712-696	6750

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EXAMINER	
GAMBEL, PHILLIP	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 11/16/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Offic
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09/335686

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.

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1644	11

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This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☑ Responsive to communication(s) filed on 9/24/01

☑ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☑ Claim(s) 44-46, 49-55 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☑ Claim(s) 44-46, 49-55 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

☆ U.S. GPO: 1998-421-632/40206

DETAILED ACTION

1. Applicant's amendment, filed 9/24/01 (Paper No. 10), has been entered. Claims 47 and 48 have been canceled. Claims 1-43 have been canceled previously. Claims 44, 49, 51 and 52 have been amended.

2. Claims 44-46 and 49-55 are pending and being acted upon presently.

3. The text of those sections of Title 35 USC not included in this Action can be found in a prior Action. This Office Action will be in response to applicant's arguments, filed 9/24/01 (Paper No. 10). The rejections of record can be found in the previous Office Action (Paper No. 9).

4. Claims 44-46 and 49-55 stand rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. The specification as originally filed does not provide support for the invention as now claimed: "wherein prolonged humoral immune that antibody production remains suppressed after the anti-gp39 has been cleared from the subject"

Applicant's amendment, filed 9/24/01 (Paper No. 10), have been fully considered but are not found convincing essentially for the reasons of record.

Applicant argues that the originally specification provides ample support for the claimed limitation, by pointing to page 12 which defines prolonged suppression to mean that suppression of the antibody production against a TD antigen is maintained after administration of a gp39 antagonist in vivo has been terminated. Applicant also points to pages 20, 21 and 25 and Figures 1B and 6B which address the half-life of anti-gp39 antibodies.

In contrast to applicant's assertions, the disclosure of the limitation of "wherein prolonged humoral immune that antibody production remains suppressed after the anti-gp39 has been cleared from the subject". "Cleared" and "prolonged suppression maintained after administration of a gp39 antagonist in vivo has been terminated" differ in scope. Further, the scope or the metes and bounds of half-life is not the same as "cleared".

Therefore, the specification as filed does not provide a sufficient written description for this phrase. The specification does not provide blazemarks nor direction for the instant methods encompassing the above-mentioned "limitations" as they are currently recited. The instant claims now recite limitations which were not clearly disclosed in the specification as-filed, and now change the scope of the instant disclosure as-filed. Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the new matter in the response to this Office action.

Alternatively, applicant is invited to provide sufficient written support for the "limitations" indicated above. See MPEP 714.02 and 2163.06

Applicant's arguments are not found persuasive.

5. Applicant's amended claims, filed 9/24/01 (Paper No. 10), obviated the previous rejections under 35 U.S.C. § 112, second paragraph.

6. Claims 44-46, 49 and 51-53 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Cobbold et al. (U.S. Patent No. 6,056,956) in view of Lederman et al. (U.S. Patent No. 5,474,771; 1449, #AA) OR Armitage et al. (U.S. Patent No. 6,087,329) for the reasons of record set forth in Paper No. 9.

Claims 50, 54, 55 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Cobbold et al. (U.S. Patent No. 6,056,956) in view of Lederman et al. (U.S. Patent No. 5,474,771; 1449, #AA) OR Armitage et al. (U.S. Patent No. 6,087,329).
as applied to claims 44- 46, 9, 51-53 above
and in further view of Ramanathan et al. (WO 91/09059) for the reasons of record set forth in Paper No. 9.

7. Applicant's amendment, filed 9/24/01 (Paper No. 10), have been fully considered but are not found convincing essentially for the reasons of record. Applicant argues that the prior art fails to suggest the claimed invention and fails to appreciate the prolonged suppression of humoral immunity achieved by the claimed coadministration.

Applicant argues that nothing in the prior art equates the effects of a CD4-specific antibody and a gp39-specific antibody.

Applicant asserts that, at best, the prior art suggest a global suppression of a humoral immune response to antigens for a transient period of time.

Applicant argues that it could not have predicted that humoral immune responses could be selectively suppressed for prolonged period of time to desired antigen in an antigen-specific manner with gp39-specific antibodies.

Furthermore, applicant submits in conjunction with instant Example 2 that it could not have been reasonably predicted prior to the present invention that humoral immunity would be suppressed to specific antigens for long periods of time even after the anti-gp39 antibody has been cleared from the subject.

In contrast to applicant assertions, the following of record is set forth to support the motivation and expectation of success at the time the invention was made to achieve the claimed limitations.

Cobbold et al. teach the use of CD4-specific antibodies to induce specific non-responsiveness or tolerance to various molecules, including globular proteins, glycoproteins and polypeptides intended for therapeutic use and allergens (see entire document; including column 2, paragraph 4; column 3, paragraphs 5-6).

Cobbold et al. differ from the claimed methods by not teaching the preferred embodiments of targeting the CD40L/gp39 with CD40L-specific antibodies.

Lederman et al. teach inhibiting various immune responses with 5C8-specific antibodies (see entire document, including columns 6-7, 11); including allergies (column 11, paragraph 6). The 5C8 specificity is the equivalent of human CD40L.

Armitage et al. teach inhibiting various immune responses with CD40 antagonists, including soluble CD40, CD40Ig, monomeric CD40L (e.g. columns 10-11, including overlapping paragraph, columns 14-17; column 21); including targeting allergies, including IL-4 induced IgE responses (e.g. column 10, paragraph 3 - column 11, paragraph 1; column 15, paragraph 1-2; Examples 8-11, 13).

In contrast to applicant's assertions of no connection between targeting CD4 and CD40L/gp39; the prior art of Cobbold et al., Lederman et al. And Armitage et al. all target the same cell, that is, the CD4 T helper cell with the motivation and expectation of success of inhibiting immune response to a broad variety of antigens, given the essential role of T helper cells in immune responses and regulation.

Also, in contrast to applicant's assertions, the prior art does teach achieving specific non-responsiveness or specific unresponsiveness to antigens of interest, including those thymus-dependent antigens encompassed by the claimed methods.

Given such specific unresponsiveness, the long term specific unresponsiveness would have been expected to be maintained for a prolonged period of time, including after clearance of CD40L-specific antibodies. This is not to say that additional treatment could be forthcoming but the ordinary artisan would have expected that prolonged suppression would have been achieved by achieving the endpoint of specific nonresponsiveness at the time the invention was made.

Given the ability of 5C8-/CD40L-specific antibodies, as taught by Lederman et al. OR the ability of various CD40 antagonists, as taught by Armitage et al. to inhibit various immune responses, including T helper cell-mediated immune responses, including humoral responses; one of ordinary skill in the art at the time the invention was made would have been motivated to substitute these antagonists into the methods of Cobbold et al. to similarly target T helper cells to inhibit humoral responses to thymus-dependent antigens. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Also, as pointed out previously, the following is noted.

Ramanathan et al. teach the use of IL-4-specific antagonists such as IL-4-specific antibodies to inhibit or treat allergic responses (see entire document, including page 1, paragraph 3; Summary of the Invention; Description f the Invention, page 6, paragraph 2, pages 13-16).

Combination therapy was known and practiced at the time the invention was made.

It is prima facie obvious to combine two compositions each of which is taught by prior art to be useful for same purpose in order to form third composition that is to be used for very same purpose; idea of combining them flows logically from their having been individually taught in prior art. In re Kerkhoven, 205 USPQ 1069, CCPA 1980. See MPEP 2144

Given the prior art teachings of using both CD40:CD40L-specific inhibitors and IL-4-specific inhibitors to inhibit allergic responses; the ordinary artisan would have been motivated to combine both said inhibitors to down regulate responses to allergens at the time the invention was made.

From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicant's arguments are not found persuasive.

8. Claims 44-46 and 49-55 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 5,942,229 for the reasons of record set forth in Paper No. 9.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims anticipate the instant method claims.

In addition, when the instant claims are read in light of the specification; the patented claims are the preferred embodiments and again anticipate the instant claims.

Applicant's amendment, filed 9/24/01 (Paper No. 10), requests that this rejection be stayed in abeyance until the subject application is otherwise in condition for allowance.

9. No claim is allowed.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Phillip Gambel, Ph.D.
Primary Examiner
Technology Center 1600
November 13, 2001

DIRECTOR TC 1600